

Appl. No. 10/027,267
Amdt. dated May 6, 2005
Reply to Office Action of February 9, 2005

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1 (currently amended): An absorbent device configured for partial disposition within the vestibule of a wearer, and for at least partially occluding the vestibule respecting fluid flow therefrom, and adapted to deliver a therapeutic agent, the device comprising:

a fluid-absorbent body having a posterior region including a raised profile an application region for projection within said vestibule intermediate the labia majora inwardly bounding same from a position posteriorly remote from the clitoris and extending to the rearwardmost aspect of the vestibule, and an anterior region merging with the posterior region for a generally external disposition about the vulvar region over the labia majora and spaced from the clitoris; and

a formulation including a therapeutic agent positioned substantially within the application region.

2 (withdrawn): The device of claim 1, wherein the body includes a cover, and wherein the therapeutic agent is formed with the cover.

3 (original): The device of claim 1, wherein the body includes a cover having a surface, and wherein the therapeutic agent is coupled to the surface.

4 (withdrawn): The device of claim 1, wherein the body includes an absorbent, and wherein the formulation including the therapeutic agent is formed with the absorbent.

5 (withdrawn): The device of claim 1, wherein the body includes an absorbent, and wherein the formulation including the therapeutic agent is contained in the absorbent.

6 (withdrawn): The device of claim 1, wherein the body includes an absorbent having a surface, and wherein the therapeutic agent is coupled to the surface.

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7 (withdrawn): The device of claim 1, further comprising a reservoir within the application region, wherein the therapeutic agent is located substantially within the reservoir.

8 (withdrawn): The device of claim 7, wherein the application region has a surface, and wherein the reservoir is in communication with the surface.

9 (withdrawn): The device of claim 7, wherein the application region has a surface, and wherein the reservoir is located under the surface.

10 (withdrawn): The device of claim 1, wherein the formulation including the therapeutic agent is substantially a liquid.

11 (withdrawn): The device of claim 1, wherein the therapeutic agent is an emulsion.

12 (original): The device of claim 1, wherein the therapeutic agent is a powder.

13 (withdrawn): The device of claim 1, wherein the therapeutic agent is a gel.

14 (withdrawn): The device of claim 1, wherein the therapeutic agent is an ointment.

15 (withdrawn): The device of claim 1, wherein the therapeutic agent is a salve.

16 (original): The device of claim 1, wherein the formulation including the therapeutic agent is substantially a solid.

17 (withdrawn): The device of claim 1, wherein the formulation including the therapeutic agent is substantially a semi-solid.

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18 (original): The device of claim 1, wherein the formulation including the therapeutic agent is encapsulated.

19 (withdrawn): The device of claim 1, wherein pressure applied by the user to the fluid-absorbent body releases the formulation including the therapeutic agent from the application region.

20 (withdrawn): The device of claim 1, wherein pressure applied by the user to the fluid-absorbent body releases the formulation including the therapeutic agent to the application region.

21 (original): The device of claim 1, wherein the therapeutic agent is adapted to treat dysmenorrhea.

22 (original): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of aspirin, ibuprofen, indomethacin, phenylbutazone, bromfenac, sulindac, nabumetone, ketorolac, mefenamic acid, and naproxen.

23 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of Lidocaine, Mepivacaine, Etidocaine, Bupivacaine, 2-Chloroprocaine hydrochloride, Procaine, and Tetracaine hydrochloride.

24 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of Diltiazem, Isradipine, Nimodipine, Felodipine, Verapamil, Nifedipine, Nicardipine, and Bepridil.

25 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of Dofetilide, E-4031, Imokalan, Sematilide, Ambasilide, Azimilide, Ted isamil, RP58866, Sotalol, Piroxicam, and Ibutilide.

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26 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of Terbutaline, Salbutamol, Metaproterenol, and Ritodrine.

27 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of nitroglycerin, isosorbide dinitrate, and isosorbide mononitrate.

28 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of Celecoxib, Meloxicam, Rofecoxib, and Flosulide.

29 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of: *Agnus castus*, aloe vera, comfrey, calendula, dong quai, black cohosh, chamomile, evening primrose, *Hypericum perforatum*, licorice root, black currant seed oil, St. John's wort, tea extracts, lemon balm, capsicum, rosemary, *Areca catechu*, mung bean, borage seed oil, witch hazel, fenugreek, lavender, and soy.

30 (withdrawn): The device of claim 1, wherein the therapeutic agent is a *Vaccinium* extract derived from a plant selected from the group consisting of: heath, cranberries, blueberries, azaleas, red onion skin, short red bell peppers, long red bell peppers, beet root extract, and capsanthin.

31 (withdrawn): The device of claim 1, wherein the therapeutic agent is selected from the group consisting of: whortleberry, lingenberry, chokeberry, sweet rowan, rowanberry, seabuckhrouberry, crowberry, strawberries, and gooseberries.

32 (withdrawn): The device of claim 1, wherein the therapeutic agent is a combination of a botanical and a beneficial agent selected from the group consisting of: vitamins, calcium, magnesium, hormones, analgesics, prostaglandin inhibitors, prostaglandin synthetase inhibitors, leukotriene receptor antagonists, essential fatty acids, sterols, anti-inflammatory agents, vasodilators, chemotherapeutic agents, and agents to treat infertility.

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33 (original): The device of claim 1, wherein the formulation includes a ligand adapted to target the therapeutic agent.

34 (original): The device of claim 1, wherein the body includes a surface, and wherein the formulation including a therapeutic agent is applied to the surface.

35 (original): The device of claim 1, wherein the body is constructed from a material, and wherein the formulation including a therapeutic agent is applied to the material before the body is constructed.

36 (original): The device of claim 1, wherein the body includes an apertured web, and wherein the formulation including a therapeutic agent is contained in the apertured web.

37 (original): The device of claim 1, wherein the formulation including a therapeutic agent is applied to degradable fibers.

38 (original): The device of claim 1, wherein the body has an interstitial space, and wherein the formulation including a therapeutic agent is interspersed within the interstitial space.

39 (original): The device of claim 1, wherein the formulation including a therapeutic agent includes a hydrogel material.

40 (original): The device of claim 1, wherein the formulation including a therapeutic agent includes a foam component.

41 (original): The device of claim 1, wherein the formulation including a therapeutic agent includes a polymeric material.

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42 (currently amended): A method for producing an absorbent device configured for partial disposition within the vestibule of a wearer, and for at least partially occluding the vestibule respecting fluid flow therefrom, and adapted to deliver a therapeutic agent, the method comprising:

manufacturing an absorbent device having a fluid-absorbent body having ~~an application region for projection within said vestibule~~ an anatomically conformable configuration with a generally ovate geometry defined about a principal longitudinal axis, a minor transverse axis and a generally orthogonal lateral axis, said pad including a laterally upward directed projecting application region lying generally along said longitudinal axis from a prominence proximate the distal end thereof and tapering both forwardly and to the opposed sides along said transverse axis; wherein said projection is configured for disposition within the vestibule of a wearer over a region bounded generally by the posterior labial commissure and the labia majora terminating proximate the latter at a location spaced from the clitoris; and

locating a formulation including the therapeutic agent substantially within the application region.

43 (original): The method of claim 42, further comprising applying a mucoadhesive adapted to enhance the contact between the absorbent article and a non-cornified epithelium of the wearer.

44 (withdrawn): The method of claim 42, wherein the manufacturing act includes manufacturing the body with a cover, wherein the formulation including the therapeutic agent is formed with the cover.

45 (original): The method of claim 42, wherein the manufacturing act includes manufacturing a body with cover having a surface, wherein the formulation including the therapeutic agent is coupled to the surface.

46 (withdrawn): The method of claim 42, wherein the manufacturing act includes manufacturing the method such that pressure applied by the wearer to the fluid-absorbent body releases the formulation including the therapeutic agent from the application region.

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47 (original): The method of claim 42, wherein the body has a surface, and wherein the locating act includes applying the formulation including a therapeutic agent to the surface.

48 (original): The method of claim 42, wherein the manufacturing act includes manufacturing the body from a material, and wherein the locating act includes applying the formulation including a therapeutic agent to the material before the body is manufactured.

49 (original): The method of claim 42, wherein the manufacturing act includes manufacturing the body to include an apertured web, and wherein the locating act includes containing the formulation including a therapeutic agent in the apertured web.

50 (original): The method of claim 42, wherein the locating act includes producing the formulation including a therapeutic agent integrally with the device.

51 (currently amended): An absorbent device configured for partial disposition within the vestibule of a wearer, and for at least partially occluding the vestibule respecting fluid flow therefrom, and adapted to deliver a therapeutic agent, the device comprising:

a fluid-absorbent body having a posterior region including a raised profile an application region for projection within said vestibule intermediate the labia majora inwardly bounding same from a position posteriorly remote from the clitoris and extending to the rearwardmost aspect of the vestibule, and an anterior region merging with the posterior region for a generally external disposition about the vulvar region over the labia majora and spaced from the clitoris; and

a means for carrying a formulation including the therapeutic agent within the application region.

52 (original): The device of claim 51, wherein the application region has a surface, and wherein the carrying means is substantially positioned adjacent the surface.

53 (withdrawn): The device of claim 51, wherein the application region has a reservoir, and wherein the carrying means is substantially positioned within the reservoir.

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54 (currently amended): A method of producing an absorbent article configured for partial disposition within the vestibule of a wearer, and for at least partially occluding the vestibule respecting fluid flow therefrom, and adapted to deliver a therapeutic agent, the method comprising:

treating a portion of a porous nonwoven sheet formed from hydrophobic polymer with a formulation including the therapeutic agent; and

forming the absorbent article so as to include absorbent material, such that the absorbent article has a posterior region including a raised profile an application region for projection within said vestibule intermediate the labia majora inwardly bounding same from a position posteriorly remote from the clitoris and extending to the rearwardmost aspect of the vestibule, and an anterior region merging with the posterior region for a generally external disposition about the vulvar region over the labia majora and spaced from the clitoris, and such that the portion of the porous nonwoven sheet at least partially covers the application region of the absorbent article.

55 (currently amended): A method of delivering a therapeutic agent through the non-cornified epithelium of the labia of a wearer, the method comprising:

disposing an absorbent article having a posterior region including a raised profile an application region for projection within said vestibule intermediate the labia majora inwardly bounding same from a position posteriorly remote from the clitoris and extending to the rearwardmost aspect of the vestibule, and an anterior region merging with the posterior region for a generally external disposition about the vulvar region over the labia majora and spaced from the clitoris at least partially within the vestibule of the wearer, the absorbent article being adapted to contact the non-cornified epithelium and deliver the therapeutic agent.

56 (withdrawn): The method of claim 55, wherein pressure applied by the wearer to the absorbent article releases the therapeutic agent.

57 (withdrawn): The method of claim 55, wherein the pressure is applied by the wearer during placement of the absorbent article.

58 (withdrawn): The method of claim 55, wherein the pressure is applied by the wearer during use of the absorbent article.

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59 (original): The method of claim 55, wherein delivery of the therapeutic agent is effected by melting a solid.

60 (withdrawn): The method of claim 55, wherein delivery of the therapeutic agent is effected by rupturing a capsule.

61 (withdrawn): The method of claim 55, wherein delivery of the therapeutic agent is effected by melting a semi-solid.

62 (original): The method of claim 55, wherein delivery of the therapeutic agent is effected by combining the therapeutic agent with a mucoadhesive that enhances the contact between the absorbent article and the non-cornified epithelium.

63 (currently amended): An absorbent device comprising:

a fluid-absorbent body having a posterior region including a raised profile an application region for projection within said vestibule intermediate the labia majora inwardly bounding same from a position posteriorly remote from the clitoris and extending to the rearwardmost aspect of the vestibule, and an anterior region merging with the posterior region for a generally external disposition about the vulvar region over the labia majora and spaced from the clitoris; and

a formulation including a therapeutic agent, wherein the application region is adapted to contact and deliver the therapeutic agent through the non-cornified epithelium of the labia.